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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,290	07/18/2003	Ronit Yahalomi	1662/611053	4123

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EXAMINER

OH, TAYLOR V

ART UNIT PAPER NUMBER

1625

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/623,290	YAHALOMI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Taylor Victor Oh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

After reviewing the set of claims 1-55 in the application, the examiner has decided to withdraw the previous Office Action and to issue another Restriction requirement.

**The Status of Claims**

Claims 1-55 are pending.

Claims 1-55 are subject to restriction.

**Election/Restriction**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4 and 41, drawn to nateglinide form C and process of making form C, classified in class 562, subclasses 445 and 450.
- II. Claims 5-9 and 43, drawn to nateglinide form J and process of making form J, classified in class 562 subclasses 445 and 450.
- III. Claims 10-14 and 45, drawn to nateglinide form K and process of making form K, classified in class 562, subclasses 445 and 450.
- IV. Claims 15-20 and 47, drawn to nateglinide form V and process of making form V, classified in class 562, subclasses 445 and 450.
- V. Claims 21-25 and 50, drawn to nateglinide form  $\beta$  and process of making form  $\beta$ , classified in class 562, subclasses 445 and 450.
- VI. Claims 26-30 and 49, drawn to nateglinide form gamma and process of making form gamma, classified in class 562, subclasses 445 and 450.

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- VII. Claims 31-39 and 53, drawn to nateglinide form epsilon and process of making form epsilon, classified in class 562, subclasses 445 and 450.
- VIII. Claim 40, drawn to nateglinide dimethyl acetamide solvate Classified in class 562, subclasses 445 and 450.
- IX. Claims 42 and 48, drawn to nateglinide n-methylpyrrolidone solvate Classified in class 562, subclasses 445 and 450.
- X. Claim 44, drawn to nateglinide dimethyl formamide solvate, classified in class 562, subclasses 445 and 450.
- XI. Claim 46, drawn to nateglinide dimethoxy ethane solvate, classified in class 562, subclasses 445 and 450.
- XII. Claims 51-52, drawn to nateglinide acetone, acetonitrile, and / or nitromethane solvate, classified in class 562\*\*\*, subclasses 445 and 450. Claims 54-55 are generic and can be prosecuted with each groups I- XII to the extend of each group.

The inventions are distinct from one and another because :

Groups I-XII are drawn to different products which must be examined based on the chemical and physical nature in comparison with those in the prior art. The search for each polymorphic form and its corresponding solvate are extremely burdensome and are not co-extensive of each other. Especially, no standard nomenclature has been assigned to various types of polymorphs, each individual polymorph must be searched

for its chemical content and structure together with many distinctive physical data for the particular form.

The inventions are distinct, each from the other because of the following reasons:

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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*Taylor Victor Oh*  
*4/17/08*